REMARKS

Claims 1 and 4-12 are pending. Claims 4 and 5 have been withdrawn from consideration.

In the final Office Action mailed May 1, 2008, claims 1, 2, and 6 have been rejected as allegedly obvious under 35 U.S.C. § 103 over U.S. Patent No. 7,087,726 to Chuntharapai et al. ("*Chuntharapai*") in view of U.S. Patent No. 5,683,712 to Cavazza ("*Cavazza*").

By the Amendment filed on November 1, 2008, Applicants amended claims 1 and 6, cancelled claim 2, and added new claims 7-12.

Applicants appreciate the time and consideration given to the undersigned by Examiners Gambel and Wen at the personal interview held at the U.S. PTO on November 20, 2008. This paper is in furtherance of the discussions at the Interview.

I. AMENDED CLAIM 1 IS SUPPORTED IN THE APPLICATION AS FILED

Claim 1 recites:

> 1. (Currently Amended) A medicament for ~~with immunotropic activity effective in~~ treating a disease of viral etiology comprising a homeopathically activated ~~one or more homeopathic dilutions of a potentiated~~ form of at least one monoclonal, polyclonal, or natural antibody~~ies~~ to ~~an~~ interferon~~,~~ wherein said homeopathically activated ~~the potentiated~~ form does not suppress the activity of the interferon~~ and wherein one or more homeopathic dilutions of the potentiated form of antibodies to the interferon being produced by a homeopathic potentiation technology~~.

It is the Applicants' understanding that the Examiners' primary objections are focused on whether the specification of the present application, together with the prior art as a whole, provided one skilled in the art with a recognition of the meaning of the term "homeopathically activated" or "homeopathically potentized." For this reason, and per discussions at the Interview, Applicants now move forward with a showing that the term "homeopathically activated" was clearly supported in the application as filed, particularly if considered together with the state of the art as a whole at the time the '652 application was filed.

Applicants submit herewith a Declaration of Dr. Epstein ("the *Epstein Declaration*") with attached Exhibits I and II. The *Epstein Declaration*, together with the attached Exhibit II, is un-rebutted evidence that the term 'potentization" (or activation as set forth in the claims) had clear meaning to one skilled in the art. The term "potentized" was used liberally in the definitive

reference text on homeopathy. The *Epstein Declaration* is also un-rebutted evidence that that the designations C12 or C30 had clear meaning to one skilled in the art. As explained in the Epstein Declaration, the German Homeophatic Pharmacopea specifically explains the standard meaning of such designation.

The specification of the '652 application describes: a) preparation of "activated" or "potentiated" antibodies to interferon by homeopathic technology (*e.g.*, Examples 1 and 2), b) administration of the activated or potentiated form of the antibody to patients (*e.g.*, Examples 4 and 5), and c) biological effects of such administration on T-cells and phagocytes (*e.g.*, Examples 2 and 3). In combination, the disclosures of the specification and the evidence submitted with the *Epstein Declaration* clearly place the "homeopathically activated form" of the antibodies to interferon in possession of the inventors as of the filing date of the above-identified application.

Applicants again note that *haec verbis* disclosure is not a pre-requisite for complying with the written description requirement. *See* MPEP § 2163. I. B. The description may be express, implicit, or inherent. *Id.* The key to evaluating compliance with the written description requirement is a determination whether the applicant had possession of the claimed invention based on the content of the application as a whole. *See* MPEP § 2163. II. The outcome of the evaluation depends on whether "the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed." *See* MPEP § 2163.01, *citing In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

On the bais of the foregoing, Applicants respectfully maintain that amended claim 1 is fully supported in the application as filed.

II. OBVIOUSNESS REJECTION OVER *CHUNTHARAPAI* IN VIEW OF *CAVAZZA*

The Examiner has rejected claims 1-2 and 6 as obvious over the combination of .*Chuntharapai* and *Cavazza*.

Applicants made arguments in regards to the *prima facie* obviousness in the Amendment submitted on November 1, 2008. Herewith, Applicants submit the *Epstein Declaration* with attached Exhibit I in further response to the Examiner's assertion of obviousness. The *Epstein Declaration* is submitted to show absence of *prima facie* obviousness, not in rebuttal of the

alleged *prima facie* case. It provides the results of the study conducted by an outside vendor to evaluate effectiveness of homeopathically activated form of antibodies to interferon. As clear from the evidence set forth in the *Epstein Declaration*, the homeopathically activated form of antibodies to interferon is far superior to placebo in a well-accepted animal model for influenza. The mean life duration of mice infected with the influenza virus and treated with the placebo was about 13 days, while the mean life duration of infected mice treated with the homeopathically activated form of antibodies to interferon claimed in the present application was about 25 days. The difference in efficacy is undoubtedly statistically significant ($p<0.001$) and cannot be ascribed to anything other than the unexpected and superior activity of the claimed preparation.

Furthermore, while not necessary to establish patentability, the study also demonstrated that the homeopathically activated form of antibodies to interferon is at least as effective or more effective than oseltamivir (TAMIFLU), a well-known and accepted pharmaceutical compound used in treating influenza. The mean life duration of mice infected with the influenza virus and treated with oseltamivir was about 21 days, while the mean life duration of infected mice treated with the homeopathically activated form of antibodies to interferon claimed in the present application was about 25 days. Applicants respectfully assert that the *Epshtein Declaration* is un-rebutted evidence of non-obviousness, and it provides further support for non-obviousness of claim 1.

Applicants respectfully submit that none of the references, alone or in combination, disclose, teach or suggest anything that would lead one skilled in the art to expect that a homeopathically activated form of an antibody to interferon would have any activity, let alone the specific activity levels reported in the *Epstein Declaration* and the Exhibit I.

On the basis of the foregoing, Applicants respectfully submit that claim 1, as amended, and dependent claims are non-obvious. Withdrawal of the rejection is respectfully requested.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711.

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